

Matthew IAMMATTEO, M.D.
Application Serial No. 10/840,131
Premenstrual Dysphoric Disorder Medication

IN THE DRAWINGS

No amendment.

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REMARKS

Applicant is grateful for the Examiner taking timely action in response to the grant of Applicant's PETITION TO MAKE EXAMINATION SPECIAL. Applicant respectfully suggests the Examiner consider listing the prior art discussed in that PETITION in a Form PTO-892, to assure that the prior art made of record in the PETITION is listed on the front page of the issued patent.

I. ANTICIPATION BY BELL ET AL.

The OFFICE ACTION rejects certain claims as anticipated by Stephen BELL et al., *Oral Contraceptives to Prevent Pregnancy*, United States Patent Publication Serial No. 2003/0139381 (24 July 2003) at claims 42, 48 and 69.

Reconsideration is requested because the reference fails to teach each limitation of the pending claims. Pending claim 1 is drawn to a three-part combination. See Matthew IAMMATTEO, RULE 132 DECLARATION (27 December 2005) at ¶¶ 6 to 8. In contrast, BELL et al. teaches two different two part combinations. *Id.*

Because BELL et al. fails to teach the claimed three-part combination, Applicant respectfully believes that BELL cannot anticipate any claim.

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II. OBVIOUSNESS OVER BELL ET AL.

The OFFICE ACTION rejects various claims as obvious in light of Stephen BELL et al. alone. Reconsideration is requested because the OFFICE ACTION fails to state a *prima facie* case of obviousness.

A *prima facie* case of obviousness requires several elements. In *re Vaack*, 947 F.2d 488 (Fed.Cir. 1991). First, the reference must teach each element of the claims at issue. Second, the reference must suggest combining the art of record to replicate the claimed invention.

In the immediate case, the reference fails to teach each element of the claims at issue. Pending claim 1 is drawn to a three-part combination. See Matthew IAMMATTEO, RULE 132 DECLARATION (27 December 2005) at ¶¶ 6 to 8. In contrast, BELL et al. teaches various two part combinations. *Id.*¹

Similarly, a *prima facie* case requires identification in the prior art of record of some suggestion to modify the prior art to reach the claimed invention. In *re Lee*, 277 F.3d 1338, 1344 (Fed.Cir., 2002). (there must be some "hint or suggestion in a particular reference"). In the immediate case, the OFFICE ACTION at page 3 says that one of ordinary skill would

¹ The OFFICE ACTION says, "Bell et al. teaches a composition comprising estrogen, progesterone and fluoxetine (See claims 48, 69 and 73 for example)." The Inventor's DECLARATION explains that this factual assertion is not precisely correct.

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have been motivated because "the composition of Bell can be formulated into transdermal patch and ring." Just because something can be done, however, does not provide any motivation to actually do it. See e.g., *In re Fritch*, 972 F.2d 1260, 1266 (Fed. Cir. 1992). The OFFICE ACTION fails to identify any suggestion in the prior art of record to modify the prior art and make the claimed combination.

Furthermore, there can be no motivation to modify a reference where the reference itself teaches that the modification would not work. See *Tec Air, Inc. v. Denso Mfg. Michigan, Inc.*, 192 F.3d 1353, 1360 (Fed.Cir. 1999). In the immediate case, the reference teaches away from the claimed three-part combination. See Matthew IAMMATTEO, RULE 132 DECLARATION (27 December 2005) at ¶¶ 9 to 10. Thus, the art of record fails to provide a motivation to make the claimed modification.

The reference fails to teach each element of the claims at issue and fails to suggest modifying the art of record to make the claimed combination. The OFFICE ACTION therefore fails to state a *prima facie* case of obviousness.

III. OBVIOUSNESS OVER STUDD ET AL. COMBINED WITH FREEMAN ET AL.

The OFFICE ACTION rejects various claims as obvious in light of J. STUDD et al., *Transdermal Estrogens for the*

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Treatment of Premenstrual Syndrome, in PROC. PLENARY SESS. 8TH WORLD CONG. GYNECOLOG. ENDOCRINOL. (December 2000) combined with Ellen W. FREEMAN et al., *Differential Response to Antidepressants*, 56 ARCH. GEN. PSYCHIAT. 932 (Oct. 1999). Reconsideration is requested because the OFFICE ACTION fails to state a prima facie case.

The OFFICE ACTION at page 4 correctly notes that FREEMAN et al. teaches that antidepressants have been investigated for premenstrual dysphoric disorder.

In contrast, STUDD et al. teaches away from using progesterone to treat premenstrual dysphoric disorder. To the contrary, STUDD et al. teaches that progesterone causes premenstrual dysphoric disorder. See Matthew IAMMATTEO, RULE 132 DECLARATION (27 December 2005) at ¶¶ 11 to 13. In so doing, STUDD et al. confirms the state of the prior art which the Inventor provides in the Specification.

There can be no motivation to modify a reference where the reference itself teaches that the combination would not work. See *Tec Air, Inc. v. Denso Mfg. Michigan, Inc.*, 192 F.3d 1353, 1360 (Fed. Cir. 1999). In the immediate case, STUDD et al. teaches away from the claimed three-part combination. See Matthew IAMMATTEO, RULE 132 DECLARATION (27 December 2005) at ¶¶ 11 to 13. Thus, the art of record fails to provide a motivation to make the claimed modification.

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Because STUDD teaches away from using progesterone to treat premenstrual dysphoric disorder, one of skill in the art would not have been motivated to combine STUDD with FRIEDMAN and use progesterone to cure premenstrual dysphoric disorder.

Furthermore, *prima facie* case of obviousness requires that the prior art teach a reasonable expectation of success. In *re Sibia Neurosciences, Inc.*, slip opinion 05-1072 (Fed. Cir., Nov. 29, 2005) at page 3; *Hodosh v. Block Drug Co., Inc.*, 786 F.2d 1136 (Fed. Cir. 1986). In the immediate case, STUDD et al. teaches that progesterone causes PMS. See Matthew IAMMATTEO, RULE 132 DECLARATION (27 December 2005) at ¶¶ 11 to 13. STUDD et al. therefore teaches a reasonable expectation of not success, but failure. *Id.*

IV. ELECTION WITH TRAVERSE

The OFFICE ACTION says that the Applicant made its election of the Group I claims without traverse. This is incorrect.

The restriction requirement is improper because the non-elected claims depend from the elected claims. The Examiner will recall that we specifically discussed this during our 9 August 2005 teleconference. During that teleconference, the Examiner mooted the issue by representing that the Examiner would *sua sponte* rejoin the non-elected claims prior to issuing

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a final action. This agreement was memorialized in the ELECTION at page 1 (9 August 2005). The Examiner has not objected to this memorialization.

Because the Examiner has conceded that he must re-join the non-elected claims, Applicant respectfully believes it incorrect for the Office to now characterize the election as having been made without traverse.

V. CONCLUSION

I trust that the Inventor's DECLARATION and my own remarks have adequately addressed the issues raised in the OFFICE ACTION. I thus respectfully think that the claims are in condition for prompt allowance.

Respectfully Submitted,
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